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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,198	04/15/2004	Maria Alexandra Glucksmann	MPI00-064CP1CN1DV1M	7650

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EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/825,198	GLUCKSMANN ET AL.	
	Examiner	Art Unit	
	Yong D. Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a divisional of 10/314,881, now issued as US Patent No. 6,767,727, which is a continuation of 09/773,426, now issued as US Patent No. 6,534,302, which is a CIP of 09/495,823, now issued as US Patent No. 6,780,627.

Claims 1-26 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7 and 12-13, drawn to DNA of SEQ ID NO:2, 4, 6, 8, 11, 12, 13 or 14, host cell comprising said DNA and a method of producing a protein, classified in class 435, subclass 196.

II. Claims 8-10 and 26, drawn to a sulfatase encoded by SEQ ID NO: 2, 4, 6, 8, 11, 12, 13 or 14 and a pharmaceutical composition comprising said sulfatase, classified in class 435, subclass 196.

III. Claim 11, drawn to antibody against the sulfatase of Invention II, classified in class 530, subclass 387.9.

IV. Claims 14-16, drawn to a method of detecting a sulfatase with an antibody and a kit, classified in class 424, subclass 130.1.

V. Claims 17-19, drawn to a method of detecting DNA and a kit, classified in class 435, subclass 6.

VI. Claims 20-21, drawn to a method of identifying compounds that bind to the polypeptide of Invention II, classified in class 514, subclass 789.

VII. Claim 22, drawn to a method of modulating the activity of the polypeptide of Invention II, classified in class 435, subclass 26.

VIII. Claim 23, drawn to a method of identifying a compound that modulates the activity of the polypeptide of Invention II, classified in class 514, subclass 789.

IX. Claim 24, drawn to a method of identifying a compound that modulates the level of expression of DNA of Invention I, classified in class 435, subclass 6.

X. Claim 25, drawn to drawn to a method of modulating the level of expression of DNA of Invention I, classified in class 435, subclass 6.

Applicants are required to elect ONE DNA sequence selected from SEQ ID NO:2, 4, 6, 8, 11, 12, 13 or 14 and/or ONE sulfatase sequence encoded by SEQ ID NO:2, 4, 6, 8, 11, 12, 13 or 14.

This is not an election of species. The polynucleotides of SEQ ID NO:2, 4, 6, 8, 11, 12, 13 or 14 and the polypeptides encoded by SEQ ID NO:2, 4, 6, 8, 11, 12, 13 or 14 are patentably distinct inventions. Each of the polynucleotides have different structure and/or function and each of the encoded polypeptides havie different structure and function, such as substrate specificity. Each of the polynucleotides and polypeptides are independent chemical entities and require independent search in the patent and non-patent literature.

The inventions are distinct, each from the other because of the following reasons:

The products groups I-III are patentably distinct inventions because groups II and III are drawn to polypeptides and group I is drawn to a polynucleotide

The polynucleotide of group I and polypeptide of group II are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. While a polypeptide of group II can made by methods using some, but not all, of the polynucleotides that fall within the scope of group I, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups I and II are patentably distinct.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be

journal articles devoted solely to polypeptides which would not have described the polynucleotide. Searching, therefore is not coextensive.

The polypeptide of group II and the antibody of group III are patentably distinct for the following reasons:

While the inventions of both group II and group III are polypeptides, in this instance the polypeptide of group II is a single chain molecule that functions as an enzyme, whereas the polypeptide of group III encompasses antibodies. Thus the polypeptide of group II and the antibody of group III are structurally distinct molecules; any relationship between a polypeptide of group II and an antibody of group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

In this case, the polypeptide of group II is a large molecule which contains potentially hundreds of regions to which an antibody may bind, whereas the antibody of group III is defined in terms of its binding specificity to a small structure within the polypeptide encoded by SEQ ID NO: 2, 4, 6, 8, 11, 12, 13 or 14. Thus immunization with the polypeptides of group II would result in the production of antibodies outside the scope of group III.

Furthermore, searching the inventions of group II and group III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-

length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group III. Furthermore, antibodies which bind to an epitope of a polypeptide of group II may be known even if a polypeptide of group II is novel. In addition, the technical literature search for the polypeptide of group II and the antibody of group III are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polynucleotide of group I and the antibody of group III are patentably distinct for the following reasons. Polypeptides, such as the antibody of group III which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group I will not encode an antibody of group III, and the antibody of group III cannot be encoded by a polynucleotide of group I. Therefore the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group I and group III would impose a serious search burden since a search of the polynucleotide of group I is would not be used to determine the patentability of an antibody of group III, and vice-versa.

Inventions I and Inventions V and IX-X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA of Invention I can be used for the production of the protein of group II or in hybridization assays. Searching groups I, V and IX-X together would impose serious search burden. Groups I, V and IX-X have a separate status in the art as shown by their different classifications. Moreover, even if the polynucleotide product were known, the method of groups V and IX-X may be novel and unobvious in the view of the preamble or active steps.

Invention II and Inventions VI-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of group II can be used for the production of antibodies against the protein. Searching the inventions of groups II, VI-VIII together would impose serious search burden. The inventions of groups II, VI-VIII have a separate status in the art as shown by their different classifications. Moreover, even if the polypeptide product were known, the methods of groups VI-VIII may be novel and unobvious in the view of the preamble or active steps.

Invention III and Invention IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product, such as performing binding assays. Searching groups III and IV together would impose serious search burden. Groups III and IV have a separate status in the art as shown by their different classifications. Moreover, even if the polynucleotide product were known, the method of groups IV may be novel and unobvious in the view of the preamble or active steps.

Inventions IV-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different function or different effects. (MPEP 806.04, 808.01). The instant specification does not disclose that these methods would be used together. The method of using a polypeptide and the method of using a polynucleotide are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent material. Therefore, the method of groups IV-X are divergent in materials and steps. Further, the distinct steps and products require separate and distinct searches. As such, it would be burdensome to search groups VIII and IX together.

Inventions VI-VIII are unrelated because the specification does not disclose that these methods would be used together. The methods are divergent in steps and have different modes of operation. Each invention performs this function using structurally and functionally divergent material. Further, the distinct steps require separate and distinct searches. As such, it would be burdensome to search groups VI-VIII together.

Inventions V and XI-X are unrelated because the specification does not disclose that these methods would be used together. The methods are divergent in steps and have different modes of operation. Each invention performs this function using structurally and functionally divergent material. Further, the distinct steps require separate and distinct searches. As such, it would be burdensome to search groups V and XI-X together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Yong D. Pak
Patent Examiner 1652